

All communications respecting this application should give the serial number, date of filing and name of the applicant.



**U. S. DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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Application Number	Filing Date	First Named Applicant	Attorney Docket Number
09/756,411	01/08/01	Lori	NIH061.1CP1C2

Examiner
L. E. Crane

Art Unit	Paper No.
1623	11

DATE MAILED: n/a

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel)

(1) Ms. Nancy W. Vensko

(3) --

(2) Examiner L. E. Crane

(4) --

Date of Interview: 02/11/03.

Type: ☒ Telephonic ☐ Personal (copy given to) ☐ applicant ☐ applicant's representative

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description: See attachment.

Agreement ☐ was reached with respect to some of all of the claims in question. ☒ was not reached

Claim(s) discussed: See page 2.

Identification of prior art discussed: See page 2.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: See p. 2.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would be allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary, A FORMAL RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP § 713.04) If a response to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, the completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign this form unless it is an attachment to another form.
PTOL-413 (amended 03/13/01)

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Art Unit 1623

INTERVIEW SUMMARY(cont.)

Claims discussed: All remaining of record, but no claims in particular.

Identification of prior art discussed: NONE.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: Applicant requested examiner's view concerning the possibility of a declaration under 37 CFR §1.132 signed by Dr. Vila and indicating predictability in the area of anti-HIV effectiveness by mixtures of antiviral nucleoside analogues and hydroxyurea. Applicant was advised that examiner continued to consider the fundamental problem of the '411 application to be lack of data in support of extrapolation from the findings of Malley and (Dr.) Vila (see also their issued patents) to the compositions of the instant claims. Applicant suggested and examiner concurred that the guidance provided by *Ex parte Balzarini* (21 USPO 2d 1892 (BPAI, 1991) applies to the instant case, but that the instant fact patterns are not precisely identical. Examiner deferred specific comment on the contents of the proposed declaration until examiner has had an opportunity to review the declaration and any other submissions by applicant.

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09/756,411	01/08/01	Lori	NIH061.1CP1C2

Examiner
L. E. Crane

Art Unit	Paper No.
1623	10

DATE MAILED: n/a

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel)

(1) Ms. Nancy W. Vensko, Esq.

(3) Ms. Marina L. Gordey, Ph.D.

(2) Examiner L. E. Crane, Ph.D., Esq.

(4) Mr. Eric Ives, Ph.D.

Date of Interview: **11/15/02.**

Type: ☐ Telephonic ☒ Personal (copy given to) ☐ applicant ☒ applicant's representative

Exhibit shown or demonstration conducted: ☐ Yes ☒ No If yes, brief description: See attachment.

Agreement ☐ was reached with respect to some of all of the claims in question. ☒ was not reached

Claim(s) discussed: See page 2.

Identification of prior art discussed: See page 2.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: See p. 2.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would be allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

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PTOL-413 (amended 03/13/01)

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Art Unit 1623

INTERVIEW SUMMARY(cont.)

Claims discussed: All remaining of record, claims 21-30 in particular.

Identification of prior art discussed: The prior art already of record.

Description of the general nature of what was agreed to if an agreement was reached, or any other comment: Applicant was advised that examiner considered the enablement issue to be governed by the guidance provided by *Gentry Gallery, Inc. v. Berkline Corp* (134 F.3d 1473, 45 USPO2d 1498 (Fed. Cir. 1998)) and, more specifically *Regents of Univ. of Cal. v. Eli Lilly & Co.* (119 F.3d 1559, 43 USPO2d 1398 (Fed. Cir. 1997)) and *Ex parte Balzarini et al.* (21 USPO2d 1892 (BPAI 1991)). Examiner also indicated that uncertainty concerning what test protocols correlate with human test results remained in the art area, citing the clear statement of Malley et al. in the '161 patent abstract that the combination of hydroxyurea and AZT was **ineffective** against HIV in cell culture, a direct **contradiction** of the allegations of the instant application. Examiner and applicant did not reach any conclusions concerning what was allowable.